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A Phase III randomised trial of perioperative chemotherapy versus surveillance in upper tract urothelial cancer

Submission date 31/01/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/01/2012	**Overall study status** Completed	
Last Edited 27/11/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-after-surgery-cancer-kidney-ureter-pout

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-002577-33

Integrated Research Application System (IRAS)
82914

ClinicalTrials.gov (NCT)
NCT01993979

Protocol serial number
11494, IRAS 82914

Study information

Scientific Title
A Phase III randomised trial of PeriOperative chemotherapy versus sUrveillance in upper Tract urothelial cancer

Acronym
POUT

Study objectives
POUT is a Phase III multicentre randomised controlled trial. The objective is to determine the efficacy, safety and effects on patients' quality of life of adjuvant chemotherapy in patients who have undergone radical nephroureterectomy for upper urinary tract transitional cell carcinoma (TCC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/NE/0332

Study design
Randomized; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Bladder Cancer, Renal Cancer; Disease: Urothelium

Interventions
Chemotherapy, Gemcitabine 1000 mg/m2 day 1 and day 8 as 30-minute intravenous infusion in 500ml sodium chloride; and

Cisplatin 70 mg/m2 day 1 as a 4-hour intravenous infusion or (for participants with a creatinine clearance of 25-49ml only) Carboplatin AUC 4.5 or AUC 5 (according to local practice)

Carboplatin will be given to patients who are fit for chemotherapy and fulfil all trial entry criteria but have GFR 30-49 ml/min.

Surveillance, Patients allocated to surveillance will be seen at 4, 7, 10 and 13 weeks post randomisation - equivalent to the end of cycle in patients receiving chemotherapy. Patients on

surveillance will then be followed up for signs of recurrence at the same intervals as those who received chemotherapy.

Follow Up Length: 60 month(s)

Added 27/11/2025:
Additional Data Linkage Information:
Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Gemcitabine, cisplatin, carboplatin

Primary outcome(s)
Disease free survival; Timepoint(s): The main time point of interest is 3 years after randomisation.

Key secondary outcome(s))
1. Acute toxicity; Timepoint(s): Whilst patients are on treatment and up to 3 months post-randomisation
2. Contralateral second primary utTCC; Timepoint(s): The primary timepoint of interest is 3 years
3. Invasive recurrence/second primary in the bladder; Timepoint(s): The primary timepoint of interest is 3 years after randomisation
4. Late toxicity; Timepoint(s): 6 months, 2 years
5. Metastasis free survival; Timepoint(s): The primary timepoint of interest is 3 years.
6. Overall survival; Timepoint(s): The primary timepoint of interest is 3 years after randomisation
7. Quality of life (QoL) as measured by the EORTC QLQ-C30 and EQ5D modules.; Timepoint(s): We are collecting information on QoL up to 2 years post randomisation
8. Treatment compliance (in the chemotherapy arm); Timepoint(s): Once chemotherapy has been completed; Trial feasibility; Timepoint(s): Defined by recruitment over the first 2 years

Completion date
21/10/2025

Eligibility

Key inclusion criteria
1. Written informed consent
2. >or =18 years of age
3. Post radical nephro-ureterectomy for upper tract tumour with predominant TCC component - squamoid differentiation or mixed TCC/ small cell carcinoma (SCC) is permitted
4. Histologically confirmed TCC staged pT2-pT4 pN0-3 M0 or pTany N1-3 M0 (providing all grossly abnormal nodes are resected). Patients with microscopically positive margins on pathology may be entered (providing all grossly abnormal disease was resected)

5. Satisfactory haematological profile (ANC> 1.5 x 109/L, platelet count 100 x 10/L) and liver function tests (bilirubin < 1.5 x ULN, AST and Alkaline phosphatase < 2.5 x ULN), Glomerular filtration rate = 30 mls/min
6. Fit and willing to receive adjuvant chemotherapy with first cycle to be commenced within 90 days of radical nephro-ureterectomy if allocated
7. WHO performance status 0-1.
8. Available for long-term follow-up; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
261

Key exclusion criteria
1. Evidence of distant metastases
2. Pure adenocarcinoma, squamous cell carcinoma or small cell or other variant histology
3. Un-resected macroscopic nodal disease
4. Concurrent muscle invasive bladder cancer (patients with concurrent Non-muscle invasive bladder cancer (NMIBC) will be eligible)
5. Glomerular filtration rate (GFR) <30 ml/minute. Gemcitabine-carboplatin can only be given for patients with suboptimal renal function for cisplatin ie for GFR 30-49ml/min. Patients with poor performance status or co-morbidities that would make them unfit for chemotherapy are ineligible for the trial
6. Significant co-morbid conditions that would interfere with administration of protocol treatment
7. Pregnancy; lactating women or women of childbearing potential unwilling or unable to use adequate non-hormonal contraception (male patients should also use contraception if sexually active)
8. Previous malignancy in the last 5 years except for previous NMIBC, adequately controlled non melanoma skin tumours, carcinoma in situ (CIS) of cervix or Lobular carcinoma in situ (LCIS) of breast or localised prostate cancer in patients who have a life expectancy of over 5 years upon trial entry

Date of first enrolment

01/03/2012

Date of final enrolment
10/11/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
15 Cotswold Road
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Sponsor information

Organisation
Institute for Cancer Research (UK)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Government

Funder Name
Clinical Trials Awards and Advisory Committee (CTAAC) (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from POUT-icrctsu@icr.ac.uk. Clinical data are available for sharing subject to

completion of a data sharing application form, approval by the trial oversight committees and completion of a data sharing agreement. Each request will be reviewed to confirm whether the existing trial consent covers the application, what anonymisation will be required and whether separate ethics approval would be required.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/04/2020	10/03/2020	Yes	No
Results article		13/02/2024	31/10/2025	Yes	No
Abstract results		20/02/2018		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes